

**PART 328—OVER-THE-COUNTER
DRUG PRODUCTS INTENDED FOR
ORAL INGESTION THAT CONTAIN
ALCOHOL**

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AUTHORITY: Secs. 201, 301, 501, 502, 503, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 371).

SOURCE: 60 FR 13595, Mar. 13, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 328 appear at 69 FR 13717, Mar. 24, 2004.

Subpart A—General Provisions

§ 328.1 Scope.

Reference in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 328.3 Definitions.

As used in this part:

(a) *Alcohol* means the substance known as ethanol, ethyl alcohol, or Alcohol, USP.

(b) *Inactive ingredient* means any component of a product other than an active ingredient as defined in § 210.3(b)(7) of this chapter.

Subpart B—Ingredients

§ 328.10 Alcohol.

(a) Any over-the-counter (OTC) drug product intended for oral ingestion shall not contain alcohol as an inactive ingredient in concentrations that exceed those established in this part, unless a specific exemption, as provided in paragraph (e) or (f) of this section, has been approved.

(b) For any OTC drug product intended for oral ingestion and labeled for use by adults and children 12 years

of age and over, the amount of alcohol in the product shall not exceed 10 percent.

(c) For any OTC drug product intended for oral ingestion and labeled for use by children 6 to under 12 years of age, the amount of alcohol in the product shall not exceed 5 percent.

(d) For any OTC drug product intended for oral ingestion and labeled for use by children under 6 years of age, the amount of alcohol in the product shall not exceed 0.5 percent.

(e) The Food and Drug Administration will grant an exemption from paragraphs (b), (c), and (d) of this section where appropriate, upon petition under the provisions of § 10.30 of this chapter. Appropriate cause, such as a specific solubility or manufacturing problem, must be adequately documented in the petition. Decisions with respect to requests for exemption shall be maintained in a permanent file for public review by the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(f) Ipecac syrup is exempt from the provisions of paragraph (d) of this section.

(g) The following drugs are temporarily exempt from the provisions of paragraphs (b), (c), and (d) of this section:

(1) Aromatic Cascara Fluidextract.

(2) Cascara Sagrada Fluidextract.

(3) Orally ingested homeopathic drug products.

[60 FR 13595, Mar. 13, 1995, as amended at 61 FR 58630, Nov. 18, 1996; 68 FR 24879, May 9, 2003]

Subpart C—Labeling

§ 328.50 Principal display panel of all OTC drug products intended for oral ingestion that contain alcohol.

(a) The amount (percentage) of alcohol present in a product shall be stated in terms of percent volume of absolute alcohol at 60 °F (15.56 °C) in accordance with § 201.10(d)(2) of this chapter.

(b) A statement expressing the amount (percentage) of alcohol present in a product shall appear prominently and conspicuously on the “principal display panel,” as defined in § 201.60 of